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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,567	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 12-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-7, and 12-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1, 3, 5-7, and 12-29 are pending.

2. The following new grounds of rejections are necessitated by the amendment filed 10/23/03.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 5-7, and 12-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria in the rumen or intestinal tracts of said food animal wherein the colony-forming bacteria are selected from the group consisting of *P. anaerobius, C. sticklandii, C. aminophilium, E. Coli, Listeria, Salmonella* and *Campylobacter* produced by the method inoculating female birds, in or about to reach their egg laying age, with said colony-forming bacteria; allowing a period of time sufficient to permit the production in the bird of antibody to said targeted immunogen; Harvesting the eggs laid by the birds; Separating the antibody-containing contents of said eggs from the shells and Drying said separated antibody-containing contents of said eggs, **does not** reasonably provide enablement for *any* microbial adherence inhibitor for administration to food animal or any living being to inhibit the adherence of any colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by inoculating female chickens or birds *any* target colony-forming immunogen as set forth in claims 1, 3, 5-7, and 12-29 to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable

one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only five microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming bacteria selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157* to inhibit the adherence of said colony-forming bacteria in the rumen or intestinal track and thereby decreasing the waste of dietary protein and promoting the growth of the food animal. The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157*, harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to make much less how to use any microbial adherence inhibitor in form of egg antibody that binds to *any* undisclosed colony-forming immunogen because "immunogen" could be peptide, protein, bacteria, virus, or parasite. However, peptide or protein antigen without the specific amino acid sequence has no structure. Further, there is inadequate guidance as to which undisclosed colony forming immunogen such as bacteria, parasite, or virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the colony-forming immunogen such as bacteria, virus, or parasite has been identified, the microbial adherence inhibitor in form of egg antibody to that binds to the undisclosed colony-forming immunogen cannot be made. Given the indefinite number of colony-forming immunogen, there is insufficient guidance as to the binding specificity of the microbial adherence inhibitor.

Stryer *et al*, of record, teach that a protein (immunogen) is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages). Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al*, of record, teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Given the indefinite number of undisclosed colony-forming immunogen, it is unpredictable which undisclosed microbial inhibitor in the form of chicken antibody IgY including IgA and IgM in the albumin would bind specifically to said undisclosed colony-forming immunogen, in turn, would be useful for inhibiting the adherence of any protein wasting immunogen (bacteria) in the food animals or living being. Given the indefinite number of undisclosed microbial adherence inhibitor, there is no *in vivo* working example demonstrating that the claimed microbial adherence inhibitor is effective for inhibiting the adherence of all colony-forming immunogen (bacteria, parasites, virus, etc), let alone preventing (claim 22) the adherence of targeted colony-forming immunogens in the rumen or intestinal tracts of food animal.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

5. Claims 1, 3, 5-7, and 12-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* microbial adherence inhibitor for administration to food animal or any living being to inhibit the adherence of any colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by inoculating female chickens or birds *any* target colony-forming immunogen as set forth in

claims 1, 3, 5-7, and 12-29 to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

The specification discloses only five microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming bacteria selected from the group consisting of *P. anaerobius, C. Sticklandii, C. aminophilum, E coli serogroup 0157* to inhibit the adherence of said colony-forming bacteria in the rumen or intestinal track and thereby decreasing the waste of dietary protein and promoting the growth of the food animal. The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius, C. Sticklandii, C. aminophilum,* and *E coli* serogroup *0157,* harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

Other the specific microbial adherence inhibitor that inhibits the specific colony forming bacteria *P. anaerobius, C. sticklandii, C. aminophilium, E coli, Listeria, Salmonella* from adhering to the rumen or digestive track of food animal, there is inadequate written description about the microbial adherence inhibitor that inhibit the adherence of which undisclosed colony-forming immunogen because "immunogen" could be peptide, or protein antigen and without the specific amino acid sequence, it has no structure. Further, there is inadequate written description about which undisclosed colony forming immunogen such as bacteria, parasite, and virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the colony-forming immunogen has been identified, the microbial adherence inhibitor in form of egg antibody to that binds to the undisclosed colony-forming immunogen cannot be made. Given the infinite number of undisclosed colony-forming immunogen, the said undisclosed colony forming immunogen has been adequately described, the binding specificity of microbial adherence inhibitor in the form of IgY including IgA and IgM is not adequately described.

Since the specification discloses only a microbial inhibitor produced by inoculating with the following six colony-forming immunogens such as bacteria selected from the group consisting of *P. anaerobius, C. Sticklandii, C. aminophilum, E coli* serogroup 0157: H7, *Salmonella,* and *Campylobacter*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of colony-forming immunogens, in turn, the microbial inhibitor to said undisclosed colony-forming

immunogens. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. Claims 5, 6-7, 12, and 22-29 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The "living being" in Claims 5, 6, 12, 22, 23, 26 and 28 represents a departure from the specification and the claims as originally filed. The passages pointed out by applicant in the amendment filed 10/23/03 do not provide a clear support for the said phrase.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1, 3, and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "protein wasting immunogen" in claim 1 has no antecedent in the preamble. The preamble of claim 1 recites "targeted colony-forming immunogen".

The term "substantially prevent" in claim 22 is not defined in the specification. One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3, 5, 13, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that inhibits the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claims 1 and 5 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA

immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals.

The claimed invention in claim 3 differs from the teachings of the reference only that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 13 differs from the teachings of the reference only that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*.

The claimed invention in claim 16 differs from the teachings of the reference only that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. sticklandii*.

The claimed invention in claim 19 differs from the teachings of the reference only that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. aminophilium*.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent for the *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* as taught by Krause *et al* for producing egg antibody and drying the separated entire contents whole egg (white and yolk) antibody without first isolating the antibodies from the yolk as taught by the '489 patent since (IgY) is primary the immunoglobulin isotype from the egg

yolk while IgM and IgA are mainly found in the albumin as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '489 patent teaches that antibodies without separation have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document).

Applicants' arguments filed 10/23/03 have been fully considered but are not found persuasive.

Applicants' position is that (1) there is no disclosure in Tokoro ('895 patent) of an IgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and ms an additive to food for animals. Tokoro does not provide a teaching of a microbial adherence inhibitor produced by the method of promoting the growth of food animals by binding IgY immunoglobulin combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.anaerobius, CS antigen from *Csticklandii*, and CA antigen from Caminophilium, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and reduce the ability of the immunogens to multiply. (2) Tokoro teaches separating the IgY from the yolk and does not teach using the entire contents of the harvested eggs. (3) Tokoro does not teach antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs.

In contrast to applicants' assertion that there is no disclosure in Tokoro of an IgY immunoglobulin that binds to a colony-forming immunogen, the '895 patent teaches IgY immunoglobulin that binds to a colony-forming immunogen such as E coli (See column 5, lines 29-30, in particular). The reference egg yolk inherently contains the IgY immunoglobulins while the reference albumin inherently contains the IgM and IgA class of immunoglobulins that help IgY immunoglobulin to inhibit the adherence of E coli to the rumen or intestinal tract.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P.anaerobius*, CS antigen from *Csticklandii*, and CA antigen from *Caminophilium*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Tokoro does not teach separating the entire contents of said harvested eggs, the '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

In response to applicant's argument that Tokoro does not teach antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs, Kaspers *et al* teach IgG (IgY) is the primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

11. Claims 14-15, 17-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449) and Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 1, 3, 5, 13, 16 and 19 and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Kasper et al, the '489 patent, and Krause et al have been discussed supra.

The claimed invention in claim 14 differs from the combined teachings of the references only that the microbial adherence inhibitor wherein the drying of the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs.

The claimed invention in claim 15 differs from the combined teachings of the references only that the microbial adherence inhibitor wherein the dry feed materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches high performance palatable horse feed carrier such as soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat the feed carrier material as taught by the '878 patent with the entire contents of said eggs containing antibody to *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* as taught by the '895 patent, Kasper et al, the '489 patent, and Krause et al on the feed material such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) and Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 5 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY

immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and wherein the colony-forming immunogen is from the class consisting of *Listeria, Salmonella* and *Campylobacter.*

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference antibody is inherently is a microbial adherence inhibitor that is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *E coli, Listeria, Salmonella and Campylobacter*, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Yokoyama *et al* teach a microbial adherence inhibitor such as chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane

proteins (OMP) of Salmonella. The reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the *E coli* as taught by the '895 patent for the *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent or the *Salamonella* as taught by Sugita-Konishi *et al* or the (OMP) of Salmonella as taught by Yokoyama *et al* for a microbial adherence inhibitor in the form of IgY, IgA and IgM antibody as taught by Kaspers *et al* to *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent, Sugita-Konishi *et al* or Yokoyama *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Yokoyama *et al* teach IgY antibody to colony-forming immunogen such as Salmonella inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). Sugita-Konishi *et al* teach that egg antibody to *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). The '018 patent teaches that IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular) is useful for a method of passive immunity (See abstract, in particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is the primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

Applicants' arguments filed 10/23/03 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims have been amended. (2) The Sugita-Konishi et al publication discloses IgY immunoglobulin was isolated from the egg yolk of hens immunized with 26 strains of bacteria. The investigation of the function of isolated IgY immunoglobulin was limited to three infectious bacterial strains. There is no disclosure in Sugita-Konishi et al of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins. (3) The Yokoyama et al publication discloses isolation of antibodies from chicken egg yolk immunoglobulin G (IgG) egg yolk was diluted with distilled water and mixed with ethyl alcohol. The mixture was centrifuged. (3) There is no evidence of a motivation that would impel one skilled in the art to make and use the microbial adherence inhibitor produced by the claimed method. (4) There is no suggestion to make the combination with structure shown and claimed.

However, the responses to the '895 patent have been discussed supra and incorporated here by reference.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

13. Claims 6-7, 12, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), Yokoyama *et al* (of record, Vaccine 16(4): 388-93, Feb 1998; PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claims 6 and 12 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and coating said dry feed carrier material with the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming

immunogen in the digestive track by binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulin.

The claimed invention in claim 12 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by drying the entire contents of the eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the lumen or intestinal tracts of the food animals by binding to the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the lumen or intestinal tracts of the animals and coating said dry feed carrier material with the separated entire contents of said eggs is achieved by coating feed carrier material with entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive track by binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulin wherein the colony forming immunogens are from the class consisting of *E. Coli, Listeria, Salmonella* and *Campylobacter.*

The claimed invention in claims 7 and 23 differs from the combined teachings of the references only that the microbial adherence inhibitor wherein the dry feed materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *E coli, Listeria, Salmonella and Campylobacter*, allowing a period of time sufficient to permit the

production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference IgY inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Yokoyama *et al* teach a microbial adherence inhibitor in the form of chicken egg yolk homotypic antibodies (IgY) specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella. The reference IgY inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to produce IgY antibodies that bind to colony forming immunogen in the digestive tract such as *E. Coli* as taught by the '895 patent or *Listeria, Salmonella* and *Campylobacter* as taught by the '018 patent that inhibits the adhesion of said immunogen to the digestive tract as taught by Sugita-Konishi *et al and* Yokoyama *et al* by incoculating the birds

with said immunogen, harvesting the eggs laid by the birds, separating the entire contents of harvested eggs from the shells as taught by the '895 patent, the '018 patent and coating the dry feed carrier such as soybean hulls, rice hulls and cottonseed hulls as taught by the '867 patent, and the '878 patent with the entire contents of the eggs (whole egg) as taught by the '489 patent that contains IgY in the yolks while IgM and IgA immunoglobulins in the albumin of the egg as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '895 patent teaches that egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular). Sugita-Konishi *et al* teach IgY antibody obtained from hens immunized with *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach that IgY inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

14. Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (or record, Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The '895 patent teaches a microbial adherence inhibitor such as a yolk antibody that prevent the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying female birds such as chicken in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 24 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by inoculating female birds, in or about to reach their egg laying age, with P antigen with *P. anaerobius,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the

birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

The claimed invention in claims 25, 27 and 29 differs from the teachings of the reference only that the microbial adherence inhbitor wherein the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 26 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by inoculating female birds, in or about to reach their egg laying age, with P antigen with CS antigen from *C. sticklandii,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

The claimed invention in claim 28 differs from the teachings of the reference only that the microbial adherence inhbitor is produced by inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilium,* allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; Harvesting the eggs laid by the birds; Separating the entire contents of said harvested eggs from the shells; Providing a dry feed carrier material; and Coating said dry feed carrier material with the separated entire contents of

said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent for the immunogen such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or*

Clostridium aminophilium as taught by Krause *et al* to produce IgY antibodies that bind to said colony forming immunogen in the digestive tract that inhibits the adhesion of said immunogen in the digestive track by immunizing hens with said immunogens, harvesting the eggs laid by the birds as taught by the '895 patent and the '018 patent and coating the dry feed carrier such as soybean hulls, rice hulls and cottonseed hulls as taught by the '867 patent, and the '878 patent with the entire contents of the eggs (whole egg) as taught by the '489 patent that contains IgY in the yolks while IgM and IgA immunoglobulins in the albumin of the egg as taught by Kaspers *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '895 patent teaches that egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen which is useful for a method of passive immunity (See abstract, in particular). Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 8:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist (customer service) whose telephone number is (703) 872-9305.

18. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The IFW official Fax number is (703) 872-9306.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
January 26, 2004

Christina Chan
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